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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2010

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-32979

Threshold Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**94-3409596**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1300 Seaport Boulevard, Suite 500
Redwood City, CA 94063
(Address of principal executive offices, including zip code)

(650) 474-8200
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, non accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

On October 31, 2010, there were 33,702,242 shares of common stock, par value $0.001 per share, of Threshold Pharmaceuticals, Inc. outstanding.

Threshold Pharmaceuticals, Inc.

FORM 10-Q
THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010

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The terms "Threshold," "we," "us," "the Company" and "our" as used in this report refer to Threshold Pharmaceuticals, Inc. Trademarks, tradenames and service marks used in this report are the property of their respective owners.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	September 30, 2010	December 31, 2009 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,939	$ 8,934
Marketable securities	16,113	28,381
Prepaid expenses and other current assets	765	10,342
Total current assets	20,817	47,657
Property and equipment, net	344	505
Restricted cash and other assets	761	523
Total assets	$ 21,922	$ 48,685
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 471	$ 284
Accrued clinical and development expenses	2,229	1,618
Accrued liabilities	636	10,972
Total current liabilities	3,336	12,874
Warrant liability	7,061	12,665
Deferred rent	318	489
Total liabilities	10,715	26,028
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 2,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value, shares authorized: 150,000,000 shares at September 30, 2010 and 50,000,000 at December 31, 2009; issued and outstanding: 33,702,242 shares at September 30, 2010 and 33,563,670 shares at December 31, 2009	34	33
Additional paid-in capital	231,090	230,441
Accumulated other comprehensive gain (loss)	4	(24)
Deficit accumulated during the development stage	(219,921)	(207,793)
Total stockholders' equity	11,207	22,657
Total liabilities and stockholders' equity	$ 21,922	$ 48,685

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine months Ended September 30,		Cumulative Period from October 17, 2001 (date of inception) to September 30, 2010
	2010	2009	2010	2009	
Revenue	$ —	$ —	$ —	$ —	$ 5,027
Operating expenses:					
Research and development	4,773	3,973	14,194	11,719	173,904
General and administrative	1,297	1,235	3,591	4,115	62,117
Total operating expenses	6,070	5,208	17,785	15,834	236,021
Loss from operations	(6,070)	(5,208)	(17,785)	(15,834)	(230,994)
Interest income (expense), net	14	12	53	(37)	8,312
Other income (expense)	148	(957)	5,604	(3,044)	3,293
Net loss	(5,908)	(6,153)	(12,128)	(18,915)	(219,389)
Dividend related to beneficial conversion feature of redeemable convertible preferred stock	—	—	—	—	(40,862)
Net loss attributable to common stockholders	$ (5,908)	$ (6,153)	$(12,128)	$(18,915)	$ (260,251)
Net loss per common share, basic and diluted	$ (0.18)	$ (0.40)	$ (0.36)	$ (1.24)	
Weighted average number of shares used in per common share calculations: basic and diluted	33,672	15,227	33,638	15,223	

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine months Ended September 30,		Cumulative Period from October 17, 2001 (date of inception) to September 30, 2010
	2010	2009	
Cash flows from operating activities:			
Net loss	$(12,128)	$(18,915)	$ (219,389)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	399	521	4,726
Stock-based compensation expense	509	1,601	38,514
Change in common stock warrant value	(5,604)	3,044	(3,293)
Amortization of debt issuance costs	—	—	44
Loss on sale of investments, property and equipment	—	—	(27)
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	9,326	(10,636)	(1,056)
Accounts payable	187	(323)	471
Accrued clinical and development expenses	611	730	2,229
Accrued liabilities	(10,336)	10,515	636
Deferred rent	(171)	(49)	318
Net cash used in operating activities	(17,207)	(13,512)	(176,827)
Cash flows from investing activities:			
Acquisition of property and equipment	(108)	(23)	(5,096)
Acquisition of marketable securities	(12,562)	(7,622)	(193,132)
Proceeds from sales and maturities of marketable securities	24,729	10,215	177,077
Restricted cash	12	—	(471)
Net cash provided by (used in) investing activities	12,071	2,570	(21,622)
Cash flows from financing activities:			
Proceeds from redeemable convertible preferred stock, net	—	—	49,839
Proceeds from issuance of common stock and warrants, net of offering expenses	141	18	152,549
Proceeds from issuance of notes payable	—	—	3,616
Repayment of notes payable	—	(337)	(3,616)
Net cash (used in) provided by financing activities	141	(319)	202,388
Net increase (decrease) in cash and cash equivalents	(4,995)	(11,261)	3,939
Cash and cash equivalents, beginning of period	8,934	15,466	—
Cash and cash equivalents, end of period	$ 3,939	$ 4,205	$ 3,939
Supplemental schedule of non-cash investing and financing activities			
Deferred stock-based compensation	$ —	$ —	$ 19,511
Cumulative effect of change in accounting principle — Reclassification of common stock warrants to liability upon adoption of ASC 815	$ —	$ 532	$ 532
Change in unrealized gain (loss) on marketable securities	$ 28	$ (17)	$ 4
Conversion of redeemable preferred stock	$ —	$ —	$ 49,839
Dividend related to beneficial conversion feature of redeemable convertible preferred stock.	$ —	$ —	$ 40,862

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1—ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company

Threshold Pharmaceuticals, Inc. (the "Company") is a biotechnology company focused on the discovery and development of drugs targeting the microenvironment of solid tumors. The Company was incorporated in the State of Delaware on October 17, 2001.

In June 2005, the Company formed a wholly-owned subsidiary, THLD Enterprises (UK), Limited in the United Kingdom for purposes of conducting clinical trials in Europe. There is currently no financial activity related to this entity.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments necessary for the fair statement of results for the periods presented, have been included. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year or any other interim period.

The preparation of condensed consolidated financial statements requires management to make estimates and assumptions that affect the recorded amounts reported therein. A change in facts or circumstances surrounding the estimate could result in a change to estimates and impact future operating results.

The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim unaudited condensed consolidated financial statements have read or have access to the audited consolidated financial statements for the preceding fiscal year. The condensed consolidated balance sheet at December 31, 2009 has been derived from the audited financial statements at that date but does not include all the information and footnotes required by accounting principles generally accepted in the United States of America. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2009 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 8, 2010.

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, and reflect the elimination of intercompany accounts and transactions.

Liquidity

The Company has product candidates in various stages of development as well as discovery and, since inception, has devoted substantially all of its time and efforts to performing research and development, raising capital and recruiting personnel. The accompanying consolidated financial statements of the Company were prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred significant losses since its inception. At September 30, 2010, the Company had an accumulated deficit of $219.9 million.

The Company expects to need to raise additional capital or incur indebtedness to continue to fund its future operations. The Company may seek to raise capital through a variety of sources, including:

- the public equity market;
- private equity financing;
- collaborative arrangements; and/or
- public or private debt.

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company's ability to raise additional funds will depend on its clinical and regulatory events, its ability to enter into collaboration or license agreement with others and factors related to financial, economic and market conditions, many of which are beyond its control. The Company cannot be certain that sufficient funds will be available when required or on satisfactory terms. If adequate funds are not available, the Company may be required to significantly reduce or refocus its operations or to obtain funds through arrangements that may require the Company to relinquish rights to certain of its products, technologies or potential markets, any of which could delay or require that the Company curtail its development programs or otherwise have a material adverse effect on its business, financial condition and results of operations. In addition, the Company may have to delay, reduce the scope of or eliminate some of its research and development, which could delay the time to market for any of its product candidates, if adequate funds are not available. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders.

Recent Accounting Pronouncements

In April 2010, the FASB issued Accounting Standards Update ("ASU") No. 2010-17,*Revenue Recognition — Milestone Method.* This ASU provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. Under the milestone method of revenue recognition, consideration that is contingent upon achievement of a milestone in its entirety can be recognized as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. This standard provides the criteria to be met for a milestone to be considered substantive which includes that: a) performance consideration earned by achieving the milestone be commensurate with either performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from performance to achieve the milestone; and b) relate to past performance and be reasonable relative to all deliverables and payment terms in the arrangement. This standard is effective on a prospective basis for milestones in fiscal years and interim periods within those years beginning on or after June 15, 2010, with early adoption permitted, and applies to milestones achieved on or after that time. Adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

In January 2010, the FASB issued ASU No. 2010-6,*Fair Value Measurements and Disclosures*, to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. ASU 2010-6 requires new disclosures on the transfers of assets and liabilities between Level 1 (quoted prices in active market for identical assets or liabilities) and Level 2 (significant other observable inputs) of the fair value measurement hierarchy, including the reasons and the timing of the transfers. Additionally, this guidance requires a roll forward of activities on purchases, sales, issuance, and settlements of the assets and liabilities measured using significant unobservable inputs (Level 3 fair value measurements). ASU 2010-6 became effective for the Company on January 1, 2010, except for the disclosure on the roll forward activities for Level 3 fair value measurements, which will become effective for the Company on January 1, 2011. Other than requiring additional disclosures, adoption of this new guidance did not have a material impact on the Company's condensed consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, Revenue Recognition (Topic 605):*Multiple Deliverable Revenue Arrangements – A Consensus of the FASB Emerging Issues Task Force."* This update provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific nor third-party evidence is available. The Company will be required to apply this guidance prospectively for revenue arrangements entered into or materially modified after January 1, 2011; however, earlier application is permitted. The Company does not expect that this update will have a material impact on its condensed consolidated financial statements.

NOTE 2—NET LOSS PER COMMON SHARE

Basic net loss per common share is computed by dividing net loss per share by the weighted-average number of vested common shares outstanding during the period. Diluted net loss per common share is computed by giving effect to all potential dilutive common shares, including outstanding options and warrants. A reconciliation of the numerator and denominator used in the calculation is as follows (in thousands, except per share amounts):

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Three Months Ended September 30,		Nine months Ended September 30,	
	2010	2009	2010	2009
Numerator:				
Net loss	$ (5,908)	$ (6,153)	$(12,128)	$(18,915)
Denominator:				
Weighted average common shares outstanding	33,672	15,227	33,638	15,223
Basic and diluted net loss per share	$ (0.18)	$ (0.40)	$ (0.36)	$ (1.24)

The following outstanding warrants, options and purchase rights under the Company's 2004 Employee Stock Purchase Plan were excluded from the computation of diluted net loss per share for the periods presented because including them would have had an antidilutive effect (in thousands):

	As of September 30,	
	2010	2009
Shares issuable upon exercise of warrants	10,918	3,588
Shares issuable upon exercise of stock options	2,710	940
Shares issuable related to the ESPP	40	31

NOTE 3—STOCKHOLDERS' EQUITY

Common Stock Warrants

The Company accounts for its common stock warrants under guidance now codified in ASC 815 that clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify for classification as liabilities. The guidance required the Company's outstanding warrants to be classified as liabilities and to be fair valued at each reporting period, with the changes in fair value recognized as other income (expense) in the Company's consolidated statement of operations.

At September 30, 2010, the Company had warrants outstanding to purchase 3,588,221 and 7,329,819 shares of common stock from its August 2008 and October 2009 offerings, respectively. The fair value of these warrants on September 30, 2010 was determined using a Black-Scholes valuation model with the following level 3 inputs:

	September 30, 2010	
	August 2008 Offering	October 2009 Offering
Risk-free interest rate	0.64%	0.96%
Remaining expected life (in years)	2.92	4.02
Dividend yield	—	—
Volatility	94%	87%
Stock price	$ 1.27	$ 1.27

The following table sets forth the Company's financial liabilities subject to fair value measurements as of September 30, 2010:

(in thousands)	Fair Value as of September 30, 2010	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Common stock warrants	$ 7,061	$ —	$ —	$ 7,061

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table is a reconciliation of the warrant liability, related to warrants issued in the August 2008 and October 2009 offerings, measured at fair value using level 3 inputs (in thousands):

	Warrant Liability
Balance at December 31, 2009	$ 12,665
Change in fair value of common stock warrants	(5,604)
Balance at September 30, 2010	$ 7,061

NOTE 4—STOCK BASED COMPENSATION

The Company recognizes stock-based compensation in accordance with ASC 718, *"Compensation—Stock Compensation,"* using the modified prospective transition method. Under this transition method, stock-based compensation cost recognized for the three and nine months ended September 30, 2010 and 2009 includes:

- compensation cost for all unvested stock-based awards as of January 1, 2006 that were granted after the Company's initial public offering in February 2005, and prior to January 1, 2006, that were earned during the three and nine months ended September 30, 2010 and 2009, based on the recognition of the grant date fair value estimated in accordance with ASC 718 over the service period, which is generally the vesting period.
- compensation cost for all stock-based awards granted or modified after January 1, 2006, that were earned during the three and nine months ended September 30, 2010 and 2009, based on the recognition of the grant date fair value estimated in accordance with ASC 718 over the service period, which is generally the vesting period.

In addition, ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Stock-based compensation expense recognized in the unaudited condensed consolidated statement of operations related to stock options and ESPP was $0.3 million and $0.5 million for the three and nine months ended September 30, 2010, respectively, and was $0.5 million and $1.6 million for the three and nine months ended September 30, 2009, respectively.

Valuation Assumptions

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing formula and a single option award approach. This fair value is being amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period. The fair value of employee stock options and employee purchase rights under the Company's ESPP was estimated using the following weighted-average assumptions for the three and nine months ended September 30, 2010 and 2009:

	Three Months Ended September 30,		Nine months Ended September 30,	
	2010	2009	2010	2009
Employee Stock Options				
Risk-free interest rate	2.11%	1.70%	2.35%	1.70%
Expected term (in years)	6.08	5.17	5.99	5.17
Dividend yield	—	—	—	—
Volatility	86%	84%	85%	84%
Weighted-average fair value of stock options granted	$ 0.72	$ —	$ 1.05	$ 0.50
Employee Stock Purchase Plan (ESPP):				
Risk-free interest rate	0.35%	0.71%	0.40%	0.71%
Expected term (in years)	1.25	1.25	1.25	1.25
Dividend yield	—	—	—	—
Volatility	86%	67%	88%	67%
Weighted-average fair value of ESPP purchase rights	$ 0.69	$ 0.51	$ 0.80	$ 0.52

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Employee Stock-based Compensation Expense

As required by ASC 718, the Company recognized $0.3 million and $0.5 million of stock-based compensation expense related to stock options and purchase rights granted subsequent to the Company's initial public offering in February 2005, under the Company's stock option plans and ESPP, for the three and nine months ended September 30, 2010, respectively, and $0.5 million and $1.6 million of stock based compensation for the three and nine months ended September 30, 2009, respectively. As of September 30, 2010, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's stock option plans was approximately $2.1 million before forfeitures. This cost will be recorded as compensation expense on a straight-line basis over the remaining weighted average requisite service period of approximately 3.3 years.

Non-employee Stock-based Compensation Expense

The Company accounts for equity instruments issued to non-employees in accordance with ASC 505,*"Equity."* The equity instruments consisting of stock options are valued using the Black-Scholes option pricing model. The values attributable to these options are amortized over the service period and the unvested portion of these options is remeasured at each vesting date. In connection with the grant of stock options to non-employees, the Company recorded stock-based compensation of approximately $4,000 and $13,000 for the three and nine months ended September 30, 2010, respectively, and $8,000 and $18,000 for the three and nine months ended September 30, 2009, respectively.

Stock-based compensation expense, which consists of the compensation cost for employee stock options, and the value of options issued to non-employees for services rendered, was allocated to research and development and general and administrative as follows (in thousands):

	Three Months Ended September 30,		Nine months Ended September 30,	
	2010	2009	2010	2009
Amortization of stock-based compensation:				
Research and development	$ 98	$ 204	$ 248	$ 715
General and administrative	155	279	261	886
	$ 253	$ 483	$ 509	$ 1,601

Equity Incentive Plans

2004 Equity Incentive Plan Pursuant to the terms of the 2004 Equity Incentive Plan, the number of shares reserved for issuance thereunder increased by 202,401 effective January 1, 2010. On March 1, 2010 the Board of Directors approved an addition of 2,250,000 shares for issuance under the 2004 Equity Incentive Plan and on May 19, 2010 the stockholders of the Company approved the same addition of 2,250,000 shares for issuance under the 2004 Equity Incentive Plan. At September 30, 2010, 801,406 shares were authorized and available for issuance under the 2004 Equity Incentive Plan.

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes stock option activity under the Company's 2004 Equity Incentive Plan:

Options	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2009	935,660	$ 1.17	—	—
Granted	1,804,500	$ 1.46	—	—
Exercised	(20,000)	$ 1.05	—	—
Forfeitures	(10,000)	$ 1.95	—	—
Outstanding at September 30, 2010	2,710,160	$ 1.36	8.89	$160,160
Vested and expected to vest September 30, 2010	2,668,091	$ 1.36	8.88	$159,098
Exercisable at September 30, 2010	763,143	$ 1.27	7.71	$ 79,847

The total intrinsic value of stock options exercised during the nine months ended September 30, 2010 and 2009 were $15,000 and less than $1,000, respectively, as determined at the date of the option exercise. Cash received from stock option exercises was $21,000 and less than $1,000 for each of the three and nine months ended September 30, 2010 and 2009, respectively. The Company issues new shares of common stock upon exercise of options. In connection with these exercises, there was no tax benefit realized by the Company due to the Company's current loss position.

2004 Employee Stock Purchase Plan Pursuant to the terms of the 2004 Employee Stock Purchase Plan, the number of shares reserved for issuance thereunder increased by 100,000, effective January 1, 2010. For the nine months ended September 30, 2010, plan participants had purchased 118,572 shares at an average purchase price of $1.01. As of September 30, 2010, plan participants had $40,000 withheld to purchase stock on February 14, 2010, which is included in accrued liabilities on the accompanying unaudited condensed consolidated balance sheet. At September 30, 2010, 384,330 shares were authorized and available for issuance under the ESPP.

NOTE 5—FAIR VALUE MEASUREMENTS AND MARKETABLE SECURITIES

The Company accounts for its marketable securities in accordance with ASC 820*"Fair Value Measurements and Disclosures."* ASC 820 defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 - Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company's short-term investments primarily utilize broker quotes in a non-active market for valuation of these securities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company utilizes the market approach to measure fair value for its financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities. The following table sets forth the Company's financial assets (cash equivalents and marketable securities) at fair value on a recurring basis as of September 30, 2010 and December 31, 2009:

(in thousands)	Fair Value as of September 30, 2010	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	$ 3,939	$ 3,939	$ —	$ —
Certificates of deposit	4,520	—	4,520	—
Corporate bonds	1,570	—	1,570	—
U.S. Government securities	10,023	—	10,023	—
Total cash equivalents and marketable securities	$ 20,052	$ 3,939	$ 16,113	$ —

(in thousands)	Fair Value as of December 31, 2009	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	$ 7,759	$ 7,759	$ —	$ —
Certificates of deposit	12,514	—	12,514	—
Corporate bonds	1,280	—	1,280	—
U.S. Government securities	9,392	—	9,392	—
Commercial paper	6,195	—	6,195	—
Total cash equivalents and marketable securities	$ 37,140	$ 7,759	$ 29,381	$ —

The Company invests in highly-liquid, investment-grade securities. The following is a summary of the Company's available-for-sale securities at September 30, 2010 and December 31, 2009:

As of September 30, 2010 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 3,939	$ —	$ —	$ 3,939
Certificates of deposit	4,520	—	—	4,520
Corporate bonds	1,568	2	—	1,570
U.S. Government securities	10,021	2	—	10,023
	20,048	4	—	20,052
Less cash equivalents	(3,939)	—	—	(3,939)
Total marketable securities	$16,109	$ 4	$ —	$16,113

As of December 31, 2009 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 7,759	$ —	$ —	$ 7,759
Certificates of deposit	12,528	—	(14)	12,514
Corporate bonds	1,281	1	(2)	1,280
U.S. Government securities	9,401	—	(9)	9,392
Commercial paper	6,195	—	—	6,195
	37,164	1	(25)	37,140
Less cash equivalents	(8,759)	—	—	(8,759)
Total marketable securities	$28,405	$ 1	$ (25)	$28,381

There were no realized gains or losses in the three and nine months ended September 30, 2010 and 2009.

As of September 30, 2010, weighted average days to maturity for the Company's available for sale securities was 61 days, with the longest maturity being May 2011.

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of September 30, 2010, there were no marketable securities with unrealized losses.

The Company determined the fair value of the liability associated with its warrants to purchase 10.9 million shares of outstanding common stock using a Black-Scholes Model. See detailed discussion in Note 3— Stockholders' Equity.

NOTE 6—COMMITMENTS AND CONTINGENCIES

The Company leases certain of its facilities under noncancelable leases, which qualify for operating lease accounting treatment under ASC 840,*"Leases,"* and, as such, these facilities are not included on its unaudited condensed consolidated balance sheets. In February 2006, the Company entered into a new lease for an additional 34,205 square feet of space and an increase in the lease term for the existing space located at the Company's headquarters in Redwood City, California to September 30, 2011. The lease is for a period of 66 months, beginning on April 1, 2006 with respect to the additional square footage and began on March 1, 2010 with respect to the existing square footage. The lease will expire, unless otherwise terminated under the terms of the lease, on September 30, 2011. The aggregate rent for the term of the lease is approximately $4.8 million. In addition, the lease requires the Company to pay certain taxes, assessments, fees and other costs and expenses associated with the premises in amounts yet to be determined as well as a customary management fee. The Company will also be responsible for the costs of certain tenant improvements associated with the leased space. In connection with the lease, the Company furnished a letter of credit to the landlord for approximately $0.5 million.

On April 1, 2005, the Company entered into a noncancelable facilities lease agreement that originally expired on February 28, 2010 for an additional 6,489 square feet of laboratory space in Redwood City, California. On November 17, 2009, the Company extended the term of the lease agreement to expire on August 2012.

The future rental payments required by the Company for all of its facilities under noncancelable operating leases are as follows (in thousands):

Years Ending December 31,	
2010	$ 407
2011	1,284
2012	106
Total	$1,797

The Company has purchase commitments at September 30, 2010, of $1.1 million, which are primarily for the manufacture and testing of active pharmaceutical ingredient (API) or drug product for clinical testing.

Indemnification

The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, including business partners, contractors and parties performing its clinical trials. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party as a result of the Company's activities. The duration of these indemnification agreements is generally perpetual. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal. The Company maintains commercial general liability insurance and products liability insurance to offset certain of its potential liabilities under these indemnification provisions.

The Company's bylaws provide that it is required to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of a culpable nature, to the fullest extent permissible by applicable law; and to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified.

Threshold Pharmaceuticals, Inc.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Legal Proceedings

As previously disclosed, the Company, our Chief Executive Officer Harold E. Selick and our former Chief Financial Officer, Janet I. Swearson were defendants in a purported class action lawsuit alleging violations of federal securities laws pending in the United States District Court for the Northern District of California. As previously disclosed, claims against Ms. Swearson were dismissed, as were certain claims against the Company and Dr. Selick. The Company and Dr. Selick continue to deny plaintiff's allegations and any wrongdoing. The parties reached a settlement, which was approved by the Court on April 16, 2010. The $10 million amount due under the settlement was paid by the Company's insurers.

NOTE 7—COMPREHENSIVE LOSS

Comprehensive loss is comprised of net loss and other comprehensive gain (loss), which consists of unrealized gains (losses) on the Company's available-for-sale securities. The components of comprehensive loss are as follows (in thousands):

	Three Months Ended September 30,		Nine months Ended September 30,	
	2010	2009	2010	2009
Net loss	$(5,908)	$(6,153)	$(12,128)	$(18,915)
Other comprehensive gain (loss):				
Unrealized gain (loss) on marketable securities	2	—	28	(17)
Total comprehensive loss	$(5,906)	$(6,153)	$(12,100)	$(18,932)

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the "Risk Factors" section of this Quarterly Report on Form 10-Q. Other than statements of historical fact, statements made in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of Section 21E of the Exchange Act, and Section 27A of the Act. When used in this report or elsewhere by management from time to time, the words "believe," "anticipate," "intend," "plan," "estimate," "expect," and similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations. Forward-looking statements made in this report include, for example, statements about:

- the progress and timing of our clinical programs, including estimated milestones and results;
- potential benefits and uses of our product candidates including TH-302;
- estimates of future performance, capital requirements, research and development expenses and needs for and impact of financing;
- uncertainties associated with obtaining and enforcing patents and other intellectual property rights;
- the costs and timing of obtaining drug supply for our pre-clinical and clinical activities; and
- efficacy or adverse events of our products.

Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of the potential risks and uncertainties that may impact their accuracy, see the "Overview" section of this Management's Discussion and Analysis of Financial Condition and Results of Operations and the "Risk Factors" section in Part II of this quarterly report on Form 10-Q. Forward-looking statements reflect our view only as of the date of this report. We undertake no obligation to update any forward-looking statements. You should also review carefully the cautionary statements and risk factors listed in our Annual Report on Form 10-K for the year ended December 31, 2009, and in our other filings with the SEC, including our Forms 10-Q and 8-K and our Annual Report to Shareholders.

Overview

We are a biotechnology company focused on the discovery and development of drugs targeting the microenvironment of solid tumors as novel treatments for patients living with cancer. The microenvironment of solid tumors is characterized by, among other things, hypoxia or lack of oxygen, disordered blood vessel growth, and the upregulation of glucose transport. This hypoxic environment is known to be resistant to standard chemotherapy and radiation. It is thought to be responsible for the poor prognosis of many solid tumors and treating the hypoxic environment is currently believed to be a significant unmet medical need. Our product candidates are designed to selectively target the hypoxic microenvironment of tumors either by selective toxin activation in the case of our hypoxia activated prodrug (HAP) program, including TH-302, or potentially utilizing the consequences of increased uptake of glucose in cancer cells relative to most normal cells. Our product candidate glufosfamide, which we licensed to Eleison Pharmaceuticals, Inc. in October 2009, shares certain structural characteristics with glucose but acts instead as a chemotherapeutic toxin when taken up by a cell.

Our focus is on product candidates for the treatment of patients with cancer. Our clinical development efforts are currently focused on one product candidate for which we have exclusive worldwide marketing rights:

- TH-302, which we discovered, is our lead product candidate for the potential treatment of patients with cancer. It is a novel drug candidate that is activated under severe hypoxic conditions and was designed to specifically target the severe hypoxic regions that are present in most solid tumors. TH-302 is currently in Phase 1, Phase 1/2 and Phase 2 clinical trials. In June 2010, we reported updated top-line results from the Phase 1 monotherapy trial of TH-302 including updated data in patients with metastatic melanoma and small-cell lung cancer (SCLC). We also reported updated top-line interim results from each of four Phase 1/2 combination therapy investigations of a chemotherapy agent plus TH-302 including updated data in patients with first-line pancreatic cancer treated with gemcitabine plus TH-302 and in patients with soft tissue sarcoma treated with doxorubicin plus TH-302. In October 2010, we reported updated top-line results from our Phase 1/2 combination therapy trial, including updated data in patients with first-line pancreatic cancer treated with gemcitabine plus TH-302. We expect to present updated top-line results from the Phase 1 monotherapy and Phase 1/2 combination therapy trials in the fourth quarter of 2010. We also initiated two clinical studies in the second quarter of 2010: a Phase 1 open label clinical trial of TH-302 in patients with advanced leukemias and a randomized, controlled Phase 2 trial of TH-302 in combination with gemcitabine in patients with first-line pancreatic cancer. We expect to present top-line results from the Phase 1 open label clinical trial in advanced leukemias in the fourth quarter of 2010 and limited interim results from the randomized Phase 2 trial in the first half of 2011.

We are working to broaden the applicability of TH-302 to other cancers as well as to discover additional hypoxia activated prodrugs that will selectively target cancer cells.

In June 2010, at the American Society for Clinical Oncology (ASCO) 2010 annual meeting and as part of a company presentation concurrent with the meeting, we presented updated top-line efficacy results from patients in the Phase 1 clinical trial evaluating the safety and initial efficacy of TH-302 as a monotherapy in patients with advanced solid tumors. Partial responses (PRs) were documented in six of thirty-one patients (19%) with metastatic melanoma and two of eleven patients (18%) with refractory small cell lung cancer. The PRs were the best responses as assessed by RECIST (Response Evaluation Criteria In Solid Tumors). Enrollment in the study was completed in the second quarter of 2010.

Also presented at the ASCO 2010 meeting and the concurrent company presentation, were the results from the Phase 1/2 clinical trial of TH-302 in combination with doxorubicin in patients with advanced soft tissue sarcoma (the "403 trial"). Thirty-five patients had at least one evaluable post-treatment tumor assessment, including 8 patients (23%) with a partial response as measured by RECIST. Twenty-three patients (66%) achieved stable disease while 4 patients (11%) had progressive disease. Median PFS was 6.4 months (95% CI: 5.6 months to Not Reached). While myelosuppression was dose limiting; there was acceptable hematologic toxicity at the maximum tolerated dose of TH-302 (300 mg/m2). The combined regimen was well tolerated with no additive toxicity to doxorubicin and no other cumulative toxicities. Skin and mucosal toxicities were reversible and have not been dose limiting at the maximum tolerated dose. These results support additional controlled investigations in soft tissue sarcoma with TH-302 in combination with doxorubicin.

In October 2010, at the European Society for Medical Oncology (ESMO) Annual Meeting, we presented updated results from multi-armed Phase 1/2 clinical trial of TH-302, which includes three separate treatment arms, with each arm combining TH-302 with a different chemotherapeutic agent for the treatment of patients with solid tumors (the "402 trial"). The trial enrolled 160 patients including 142 patients with at least one evaluable post-treatment tumor assessment by RECIST. In the gemcitabine treatment arm, 43 patients with advanced or metastatic pancreatic cancer have had at least one evaluable post-treatment tumor assessment. The majority of those patients received TH-302 doses of 340mg/m2 or 240mg/m2. Among the patients receiving 340mg/m2 of TH-302, there was one patient with a complete response, 5 patients with a partial response, 14 patients with stable disease and one patient with progressive disease. Among the patients receiving 240mg/m2 of TH-302, there were 13 patients with stable disease and 3 patients with progressive disease. Median overall survival (OS), based upon data for all 43 patients regardless of TH-302 dose, was 11.4 months (95% CI: 6.0 to 15.8 months) and median progression-free survival (PFS) was 6.4 months (95% CI: 4.7 months to 7.7 months).

Additionally, in the TH-302 plus docetaxel or pemetrexed treatment arms of the trial, thirty-two patients with non-small cell lung cancer have had at least one evaluable post-treatment tumor assessment including 8 patients (25%) with a partial response. Fourteen patients (44%) achieved stable disease while 10 patients (31%) had progressive disease. Median PFS was 4.2 months (95% CI: 2.8 months to Not Reached). In the TH-302 plus docetaxel treatment arm, 15 patients with castration resistant prostate cancer were treated. Of the 13 patients with at least one evaluable post-treatment tumor assessment, 3 patients (23%) had a partial response, 9 patients (69%) achieved stable disease and one patient (8%) had progressive disease. Eleven of the 15 (73%) patients had a PSA reduction of greater than 50%. %. Overall in the 402 trial, myelosuppression, as manifested by reduced platelet count or reduced neutrophil count, was the primary dose limiting toxicity. Hematologic, skin and mucosal toxicities have been acceptable at the current dose levels.

We are a development stage company incorporated in October 2001. We have devoted substantially all of our resources to research and development of our product candidates. We have not generated any revenue from the sale of our product candidates, and prior to our initial public offering in February 2005, we funded our operations through the private placement of equity securities. In February 2005, we completed our initial public offering that raised net proceeds of $38.1 million, and in October 2005, we completed an offering of common stock that raised net proceeds of $62.4 million. In August 2008, we completed an offering of common stock and warrants that raised net proceeds of $16.8 million. In October 2009, we completed an offering of common stock and warrants that raised net proceeds of $33.1million. As of September 30, 2010 we had cash, cash equivalents and marketable securities of $20.1 million. Our net loss for the nine months ended September 30, 2010 was $12.1 million and our cumulative net loss since our inception through September 30, 2010 was $219.9 million.

We expect to continue to devote substantial resources to research and development in future periods as we execute our current clinical trials, start additional clinical trials and continue our discovery efforts. Research and development expenses are expected to be higher in 2010 compared to 2009 due to the continued execution of existing clinical trials and initiation of new clinical trials. We expect that our cash, cash equivalents and marketable securities as of September 30, 2010 will be sufficient to fund our projected operating requirements through the second quarter of 2011, including prosecuting our current ongoing clinical trials and conducting research and discovery efforts toward additional product candidates, working capital and general corporate purposes. We expect that we will need to raise additional capital to complete clinical trials that we started in 2010. Research and development expenses may fluctuate significantly from period to period as a result of the progress and results of our clinical trials.

Results of Operations

Revenue. No revenue was recognized for the three and nine months ended September 30, 2010 and 2009.

Research and Development. Research and development expenses were $4.8 million for the three months ended September 30, 2010 compared to $4.0 million for the three months ended September 30, 2009. The $0.8 million increase in expenses is due primarily to a $0.9 million increase in clinical development expenses and $0.1 million increase in employee-related expenses offset by a $0.2 million decrease in stock-based compensation and consulting expenses. Research and development expenses were $14.2 million for the nine months ended September 30, 2010 compared to $11.7 million for the nine months ended September 30, 2009. The $2.5 million increase in expenses is due primarily to a $2.6 million increase in clinical and development expenses, a $0.2 million increase in consulting and $0.2 million increase in personnel related expenses, partially offset by a $0.5 million decrease in stock-based compensation.

Research and development expenses by project (in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
TH-302	$4,369	$ 2,928	$11,730	$ 8,075
Discovery research	404	941	2,464	3,250
Glufosfamide	—	81	—	232
2DG	—	23	—	162
Total research and development expenses	$4,773	$ 3,973	$14,194	$11,719

Research and development expenses associated with our internally discovered compound TH-302 were $4.4 million for the three months ended September 30, 2010 and $2.9 million for the three months ended September 30, 2009. Research and development expenses associated with TH-302 were $11.7 million for the nine months ended September 30, 2010 and $8.1 million for the nine months ended September 30, 2009. TH-302 continues to progress through the 401 trial, the 402 trial and the 403 trial. Enrollment in the 401 and the 402 trials was completed in the second quarter of 2010. The 403 trial was expanded and is expected to continue to enroll patients. In addition, in June 2010 the Company initiated a Phase 2 randomized controlled combination therapy clinical trial in patients with first-line pancreatic cancer and a Phase 1 monotherapy clinical trial in patients with advanced leukemias. As result we expect our research and development expenses to increase.

Discovery research and development expenses were $0.4 million for the three months ended September 30, 2010 compared to $0.9 million for the three months ended September 30, 2009, and were $2.5 million for the nine months ended September 30, 2010 compared to $3.3 million for the nine months ended September 30, 2009. We continue to focus our efforts towards discovering and developing new drug candidates from our hypoxia activated prodrug platform.

Due to our exclusive licensing development and commercialization of glufosfamide to Eleison Pharmaceutical, Inc. in October 2009, we did not incur significant research and development expenses associated with glufosfamide for the three and nine months ended September 30, 2010. We incurred no significant expenses related to 2DG for the three and nine months ended September 30, 2010 as we are not currently planning or conducting further additional clinical trials of 2DG.

We did not track research and development expenses by project prior to 2003, and therefore we cannot provide cumulative project expenses to date. Due to the risks and uncertainties involved in discovering and developing product candidates, such as clinical trial results, regulatory approval requirements, dependence on third parties and market acceptance, which are described in the "Risk Factors" section in Part II of this Quarterly Report on Form 10-Q, we cannot reasonably estimate the costs and timing of completion of each project or when any project will result in net cash inflows.

We expect to continue to devote substantial resources to research and development in future periods as we execute our current clinical trials, start additional clinical trials and continue our discovery efforts. Research and development expenses are expected to remain higher in 2010 compared to 2009 due to the continued execution of our existing trials and the start of the two new trials for TH-302.

General and Administrative. General and administrative expenses were $1.3 million for the three months ended September 30, 2010, compared to $1.2 million for the three months ended September 30, 2009. The $0.1 million increase was primarily due to a $0.2 million increase in consulting expenses, partially offset by a $0.1 million decrease in stock-based compensation expense. General and administrative expenses were $3.6 million for the nine months ended September 30, 2010, compared to $4.1 million for the nine months ended September 30, 2009. The decrease of $0.5 million is primarily due to a $0.6 million decrease in stock-based compensation expense.

General and administrative expenses are expected to remain lower in 2010 compared to 2009 as a result of lower stock based compensation expenses and a lower allocation of facilities expenses as a result of an increase in research and development headcount.

Interest Income (Expense), Net. Interest income (expense), net for the three months and nine months ended September 30, 2010 was interest income of $14,000 and $53,000, respectively, compared to interest income for the three months ended September 30, 2009 of $12,000 and net interest expense for the nine months ended September 30, 2009 of $37,000, respectively. Interest income (expense), net for the nine months ended September 30, 2009, included $0.1 million in interest expense related to notes payable that were repaid during the six months ended June 30, 2009. Additionally, interest income declined primarily due to lower interest rates during the three and nine months ended September 30, 2010 compared to the same periods in the prior year.

Other Income (Expense). Other income (expense) was non-cash income of $0.1 million and $5.6 million, for the three and nine months ended September 30, 2010, respectively, compared to non-cash expense of $1.0 million and $3.0 million, for the three and nine months ended September 30, 2009, respectively. The non cash income for the three and nine months ended September 30, 2010 compared to the non cash expense for the three and nine months ended September 30, 2009, respectively, was due to the decline, during the second and third quarters of 2010 in fair value of outstanding warrants to purchase 10.9 million shares of common stock warrants. ASC 815 *"Derivatives and Hedging"* requires that stock warrants with certain terms need to be accounted for as a liability with changes to their fair value recognized in the consolidated statement of operations.

Liquidity and Capital Resources

We have incurred net losses of $219.9 million since inception through September 30, 2010. We have not generated and do not expect to generate revenue from sales of product candidates in the near term. From inception until our initial public offering in February 2005, we funded our operations primarily through private placements of our preferred stock. In February 2005, we completed our initial public offering of 1,018,768 shares of common stock, raising net proceeds of $38.1 million. In October 2005, we completed a public offering of 1,066,537 shares of our common stock for net proceeds of $62.4 million. On August 29, 2008, we sold to certain investors an aggregate of 8,970,574 shares of our common stock and warrants exercisable for a total of 3,588,221 shares of our common stock raising net proceeds of $16.8 million. On October 5, 2009, we sold to certain investors an aggregate of 18,324,599 shares of our common stock and warrants exercisable for a total of 7,329,819 shares of our common stock for aggregate net proceeds of $33.1 million. We had cash, cash equivalents and marketable securities of $20.1 million and $37.3 million at September 30, 2010 and December 31, 2009, respectively, available to fund operations.

Net cash used in operating activities for the nine months ended September 30, 2010 and 2009 was $17.2 million and $13.5 million, respectively. The increase of $3.7 million in cash used in operations was primarily attributable to an increase in research and development spending associated with TH-302.

Net cash provided by investing activities for the nine months ended September 30, 2010 was $12.1 million compared to $2.6 million of net cash used in investing activities for the nine months ended September 30, 2009. The $9.5 million increase in cash provided by investing activities was due primarily to the sales and maturities of marketable securities reduced by the smaller amount of purchases of marketable securities during the period consistent with our use of cash.

Net cash provided by financing activities for the nine months ended September 30, 2010 was $0.1 million, compared to $0.3 million net cash used in financing activities for the nine months ended September 30, 2009. The cash used in financing activities in the nine months ended September 30, 2009 reflects the $0.3 million of repayments of notes payable.

Obligations and Commitments

In August 2004, we entered into a noncancelable facilities sublease agreement that expired on February 28, 2010 for our headquarters in Redwood City, California. In February 2006, we entered into a lease for an additional 34,205 square feet of space and increased the lease term for the existing space located at our headquarters in Redwood City, California to September 30, 2011. The lease is for a period of 66 months, beginning on April 1, 2006 with respect to the additional square footage and began on March 1, 2010 with respect to the square footage previously leased under our August 2004 sublease agreement. The lease will expire, unless otherwise terminated under the terms of the lease, on September 30, 2011. The aggregate rent for the term of the lease is approximately $4.8 million. In addition, the lease requires us to pay certain taxes, assessments, fees and other costs and expenses associated with the premises as well as a customary management fee. We are also responsible for the costs of certain tenant improvements associated with the leased space. In connection with the lease, we furnished a letter of credit to the landlord for approximately $0.5 million.

On April 1, 2005, we entered into a noncancelable facilities lease agreement that originally expired on February 28, 2010 for an additional 6,489 square feet of laboratory space in Redwood City, California. On November 17, 2009, we extended the term of the lease agreement to expire on August 2012.

Our major outstanding contractual obligations consist of amounts due under our operating lease agreements and purchase commitments under contract research, development and clinical supply agreements. Contractual obligations and related scheduled payments as of September 30, 2010, are as follows (in thousands):

	Remainder of current year (2010)	One to three years (2011 to 2012)	Four to five years (2014 to 2015)	After five Years	Total
Facilities leases	$ 407	$ 1,390	$ —	$ —	$1,797
Purchase commitments	1,080	—	—	—	1,080
Total	$ 1,487	$ 1,390	$ —	$ —	$2,877

At Market Issuance Facility

On October 29, 2010, we entered into an at market issuance sales agreement, or sales agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $15.0 million from time to time through MLV as our sales agents. Sales of our common stock through MLV, if any, will be made on The NASDAQ Capital Market, on any other existing trading market for our common stock, to or through a market maker or as otherwise agreed by MLV and us. Subject to the terms and conditions of the sales agreement, MLV will use commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay MLV an aggregate commission rate of 3.0% of the gross proceeds of the sales price per share of any common stock sold under the sales agreement. Under certain circumstances, sales of stock under the at market issuances sales agreement could result in an adjustment to the exercise price of certain of our outstanding warrants. The number of shares we are able to sell under this arrangement will be limited in practice based on the trading volume of our common stock. As of November 4, 2010 we had not issued or sold any shares of our common stock pursuant to the Sales Agreement.

We expect annual 2010 cash requirements to be in the range of $23 million to $25 million. We believe that our cash, cash equivalents and marketable securities as of September 30, 2010 will be sufficient to fund our projected operating
requirements through the second quarter of 2011, including prosecuting our current trials, conducting research and discovery efforts towards additional product candidates, working capital and general corporate purposes. We expect that we will need to raise additional capital to complete clinical trials that we started in 2010. We intend to seek funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

We expect to need to raise additional capital or incur indebtedness to continue to fund our future operations. We may seek to raise capital through a variety of sources, including:

- the public equity market;
- private equity financing;
- collaborative arrangements;
- licensing arrangements; and/or
- public or private debt.

Our ability to raise additional funds will depend on our clinical and regulatory events, our ability to enter into collaboration or license agreements with others and factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on satisfactory terms. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. In addition, the Company may have to delay, reduce the scope of or eliminate some of its research and development, which could delay the time to market for any of its product candidates, if adequate funds are not available. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders.

In addition, our ability to raise additional capital may be dependent upon our stock being quoted on the NASDAQ Capital Market. Previously we had fallen out of compliance with continued listing requirements because our common stock did not comply with the $1.00 minimum bid price requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(a)(1) (formerly Rule Rule 4450(a)(5)). On August 13, 2008 our Board of Directors implemented a one for six reverse stock split, effective August 20, 2008, to regain compliance with the minimum bid price requirement. On September 5, 2008, the NASDAQ Stock Market notified us that we had regained compliance with the minimum bid price. Even though we regained compliance with the minimum bid price requirement, we cannot be assured that we will be able to maintain compliance with the minimum bid price requirement in the future, and our failure to do so could result in the delisting of our shares from the NASDAQ Capital Market. To maintain our listing on the NASDAQ Capital Market, we are also required, among other things, to either maintain stockholders' equity of at least $2.5 million or a market value of at least $35 million. While we currently satisfy the stockholders' equity and market value requirements, we may not continue to do so.

If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to delay, scale back, or eliminate some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses based on historical experience and on various assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. For further information on our critical accounting policies, see the discussion of critical accounting policies in our Annual Report on Form 10-K for the year ended December 31, 2009, which we filed with the Securities and Exchange Commission on March 8, 2010. There have been no material revisions to the critical accounting policies as discussed in our Annual Report on Form 10-K for the year ended December 31, 2009.

Recent Accounting Pronouncements

In April 2010, the FASB issued Accounting Standards Update ("ASU") No. 2010-17,*Revenue Recognition — Milestone Method.* This ASU provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. Under the milestone method of revenue recognition, consideration that is contingent upon achievement of a milestone in its entirety can be recognized as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. This standard provides the criteria to be met for a milestone to be considered substantive which includes that: a) performance consideration earned by achieving the milestone be commensurate with either performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from performance to achieve the milestone; and b) relate to past performance and be reasonable relative to all deliverables and payment terms in the arrangement. This standard is effective on a prospective basis for milestones in fiscal years and interim periods within those years beginning on or after June 15, 2010, with early adoption permitted, and applies to milestones achieved on or after that time. Adoption of this standard did not have a material impact on our condensed consolidated financial statements.

In January 2010, the FASB issued ASU No. 2010-6,*Fair Value Measurements and Disclosures*, to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. ASU 2010-6 requires new disclosures on the transfers of assets and liabilities between Level 1 (quoted prices in active market for identical assets or liabilities) and Level 2 (significant other observable inputs) of the fair value measurement hierarchy, including the reasons and the timing of the transfers. Additionally, this guidance requires a roll forward of activities on purchases, sales, issuance, and settlements of the assets and liabilities measured using significant unobservable inputs (Level 3 fair value measurements). ASU 2010-6 became effective for us on January 1, 2010, except for the disclosure on the roll forward activities for Level 3 fair value measurements, which will become effective for us on January 1, 2011. Other than requiring additional disclosures, adoption of this new guidance did not have a material impact on our condensed consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, Revenue Recognition (Topic 605):*Multiple Deliverable Revenue Arrangements – A Consensus of the FASB Emerging Issues Task Force."* This update provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific nor third-party evidence is available. We will be required to apply this guidance prospectively for revenue arrangements entered into or materially modified after January 1, 2011; however, earlier application is permitted. We do not expect that this update will have a material impact on our condensed consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk. Our exposure to market risk for changes in interest rates relates to our cash equivalents on deposit in highly liquid money market funds and investments in short-term marketable securities. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. We invest in high-quality financial instruments, which currently have weighted average maturity of less than one year. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. Our investment portfolio is subject to interest rate risk and will fall in value if market interest rates rise. Nevertheless, due to the short duration of our investment portfolio, we believe an increase in the interest rates of one percentage point would not be material to our financial condition or results of operations.

In addition, we do not have any material exposure to foreign currency rate fluctuations as we operate primarily in the United States. Although we conduct some clinical trials and safety studies, and manufacture some active pharmaceutical product with vendors outside the United States, most of our transactions are denominated in U.S. dollars.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Based on their evaluation as of September 30, 2010, our chief executive officer and senior director, finance and controller have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) of the Securities Exchange Act of 1934, as amended) were effective at the reasonable assurance level to ensure that the information required to be disclosed by us in reports we are required to file under the Exchange Act was recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and Form 10-Q and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the three months ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls.

Our management, including our chief executive officer and senior director, finance and controller, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Threshold Pharmaceuticals, Inc. have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control.

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and we cannot be certain that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our chief executive officer and principal financial and accounting officer have concluded, based on their evaluation, that our disclosure controls and procedures were effective as of September 30, 2010 to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Except as previously disclosed in our quarterly report on Form 10-Q for the quarter ending June 30, 2010, which we filed with the SEC on August 5, 2010, we are not a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR BUSINESS

Risks Related to Drug Discovery, Development and Commercialization

We are substantially dependent upon the success of TH-302. Clinical trials may not demonstrate efficacy or lead to regulatory approval and preliminary results may not be confirmed.

We will not be able to commercialize our drug candidates until we obtain FDA approval in the United States or approval by comparable regulatory agencies in Europe and other countries. To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. Our initial results from clinical trials of TH-302 in a limited number of patients may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Our product candidates must undergo rigorous clinical testing, the results of which are uncertain and could substantially delay or prevent us from bringing them to market.

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. Clinical trials of new drug candidates sufficient to obtain regulatory marketing approval are expensive and take years to complete.

We cannot be certain of successfully completing clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our product candidates, including the following:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;
- the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;
- clinical trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- enrollment in our clinical trials for our product candidates may be slower than we anticipate, resulting in significant delays and additional expense;
- we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and
- the effects of our product candidates on patients may not be the desired effects or may include undesirable side effects or other characteristics that may delay or preclude regulatory approval or limit their commercial use, if approved.

Completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients, which is a function of many factors, including:

- the therapeutic endpoints chosen for evaluation;
- the eligibility criteria defined in the protocol;
- the perceived benefit of the investigational drug under study;

- the size of the patient population required for analysis of the clinical trial's therapeutic endpoints;
- our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- competition for patients by clinical trial programs for other treatments.

We may experience difficulties in enrolling patients in our clinical trials, which could increase the costs or affect the timing or outcome of these clinical trials. This is particularly true with respect to diseases with relatively small patient populations.

Pre-clinical studies of our product candidates may not predict the results of their human clinical trials.

Pre-clinical studies, including studies of our product candidates in animal models of disease, may not accurately predict the result of human clinical trials of those product candidates. In particular, promising animal studies suggesting the efficacy of TH-302 for the treatment of different types of cancer may not accurately predict the ability of TH-302 to treat cancer effectively in humans. TH-302 may be found not to be efficacious in treating cancer, alone or in combination with other agents, when studied in human clinical trials.

We are subject to significant regulatory approval requirements, which could delay, prevent or limit our ability to market our product candidates.

Our research and development activities, preclinical studies, clinical trials and the anticipated manufacturing and marketing of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in Europe and elsewhere. We require the approval of the relevant regulatory authorities before we may commence commercial sales of our product candidates in a given market. The regulatory approval process is expensive and time-consuming, and the timing of receipt of regulatory approval is difficult to predict. Our product candidates could require a significantly longer time to gain regulatory approval than expected, or may never gain approval. We cannot be certain that, even after expending substantial time and financial resources, we will obtain regulatory approval for any of our product candidates. A delay or denial of regulatory approval could delay or prevent our ability to generate product revenues and to achieve profitability.

Changes in regulatory approval policies during the development period of any of our product candidates, changes in, or the enactment of, additional regulations or statutes, or changes in regulatory review practices for a submitted product application may cause a delay in obtaining approval or result in the rejection of an application for regulatory approval.

Regulatory approval, if obtained, may be made subject to limitations on the indicated uses for which we may market a product. These limitations could adversely affect our potential product revenues. Regulatory approval may also require costly post-marketing follow-up studies. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will be subject to extensive ongoing regulatory requirements. Furthermore, for any marketed product, its manufacturer and its manufacturing facilities will be subject to continual review and periodic inspections by the FDA or other regulatory authorities. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspensions of regulatory approvals, product recalls, product seizures, operating restrictions and criminal prosecution.

Our product candidates are based on targeting the microenvironment of solid tumors, which currently is an unproven approach to therapeutic intervention.

Our product candidates are designed to target the microenvironment of solid tumors by, in the case of TH-302, harnessing hypoxia for selective toxin activation or by potentially exploiting the increased uptake of glucose in cancer cells relative to most normal cells. Our product candidate 2DG shares certain structural characteristics with glucose but acts instead as poison when taken up by a cancer cell. We have not, nor to our knowledge has any other company, received regulatory approval for a drug based on either of these approaches. We cannot be certain that our approaches will lead to the development of approvable or marketable drugs.

In addition, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of drugs based on these targeting approaches, which could lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates.

Our product candidates may have undesirable side effects that prevent or delay their regulatory approval or limit their use if approved.

Certain anti-tumor drugs being developed by us, such as TH-302 and 2DG, are expected to have undesirable side effects. For example, in clinical trials of TH-302, some patients have exhibited skin and/or mucosal toxicities that have in some cases caused patients to stop or delay therapy. The extent, severity and clinical significance of these or other undesirable side effects may not be apparent initially and may be discovered or become more significant during drug development or even post-approval. These expected side effects or other side effects identified in the course of our clinical trials or that may otherwise be associated with our product candidates may outweigh the benefits of our product candidates. Side effects may prevent or delay regulatory approval or limit market acceptance if our products are approved.

Delays in clinical testing could result in increased costs to us and delay our ability to obtain regulatory approval and commercialize our product candidates.

Significant delays in clinical testing could materially impact our product development costs and delay regulatory approval of our product candidates. We do not know whether planned clinical trials will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including adverse safety events experienced during our clinical trials and delays in:

- obtaining regulatory approval to commence a clinical trial;
- obtaining clinical materials;
- reaching agreement on acceptable clinical trial agreement terms with prospective sites;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- recruiting patients to participate in a clinical trial.

We have not yet developed a commercial formulation of TH-302.

The formulation of TH-302 that we are using for clinical trials is subject to storage and handling requirements that may not be suitable for commercial product. We are working to develop a formulation of TH-302 that will be suitable for commercial product, but there can be no assurance that we will be able to do so in a timely manner, if at all. If we are not able to develop a commercial formulation, we may delay registrational trials of TH-302.

Orphan drug exclusivity affords us limited protection, and if another party obtains orphan drug exclusivity for the drugs and indications we are targeting, we may be precluded from commercializing our product candidates in those indications.

For those drugs that meet the eligible requirements, we intend to seek orphan drug designation for the cancer indications that our drug candidates are intended to treat. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is defined by the FDA as a disease or condition that affects fewer than 200,000 individuals in the United States. The company that obtains the first FDA approval for a designated orphan drug indication receives marketing exclusivity for use of that drug for that indication for a period of seven years. Orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective, or if the manufacturer is unable to assure sufficient quantity of the drug. Orphan drug designation does not shorten the development or regulatory review time of a drug.

Orphan drug exclusivity may not prevent other market entrants. A different drug, or, under limited circumstances, the same drug may be approved by the FDA for the same orphan indication. The limited circumstances include an inability to supply the drug in sufficient quantities or where a new formulation of the drug has shown superior safety or efficacy. As a result, if our product were to be approved and received orphan drug status, the FDA could still approve other drugs for use in treating the same indication covered by our product, which could create a more competitive market for us.

Moreover, due to the uncertainties associated with developing pharmaceutical products, we may not be the first to obtain marketing approval for any orphan drug indication. Even if we obtain orphan drug designation, if a competitor obtains regulatory approval for TH-302 or 2DG for the same indication we are targeting before we do, we would be blocked from obtaining approval for that indication for seven years, unless our product is a new formulation of the drug that has shown superior safety or efficacy, or the competitor is unable to supply sufficient quantities.

Even if we obtain regulatory approval, our marketed drugs will be subject to ongoing regulatory review. If we fail to comply with continuing United States and foreign regulations, we could lose our approvals to market drugs and our business would be seriously harmed.

Following initial regulatory approval of any drugs we may develop, we will be subject to continuing regulatory review, including review of adverse drug experiences and clinical results that are reported after our drug products become commercially available. This would include results from any post-marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will also be subject to periodic review and inspection by the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. We and our contract manufacturers will be subject to ongoing FDA requirements for submission of safety and other post-market information. If we and our contract manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;
- suspend or terminate any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations;
- close the facilities of our contract manufacturers; or
- seize or detain products or require a product recall.

The FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses and marketing of pharmaceutical products.

FDA rules for pharmaceutical promotion require that a company not promote an unapproved drug or an approved drug for an unapproved use. In addition to FDA requirements, regulatory and law enforcement agencies, such as the United States Department of Health and Human Services' Office of Inspector General and the United States Department of Justice, monitor and investigate pharmaceutical sales, marketing and other practices. For example, sales, marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, as amended, and similar state laws. In recent years, actions by companies' sales forces and marketing departments have been scrutinized intensely to ensure, among other things, that actions by such groups do not qualify as "kickbacks" to healthcare professionals. A "kickback" refers to the provision of any item of value to a healthcare professional or other person in exchange for purchasing, recommending, or referring an individual for an item or service reimbursable by a federal healthcare program. These kickbacks increase the expenses of the federal healthcare program and may result in civil penalties, criminal prosecutions, and exclusion from participation in government programs, any of which would adversely affect our financial condition and business operations. In addition, even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Comparable laws also exist at the state level.

We are, and in the future may be, subject to new federal and state requirements to submit information on our open and completed clinical trials to public registries and databases.

In 1997, a public registry of open clinical trials involving drugs intended to treat serious or life-threatening diseases or conditions was established under the Food and Drug Administration Modernization Act, or FDMA, in order to promote public awareness of and access to these clinical trials. Under FDMA, pharmaceutical manufacturers and other clinical trial sponsors are required to post the general purpose of these clinical trials, as well as the eligibility criteria, location and contact information of the clinical trials. Since the establishment of this registry, there has been significant public debate focused on broadening the types of clinical trials included in this or other registries, as well as providing for public access to clinical trial results. A voluntary coalition of medical journal editors has adopted a resolution to publish results only from those clinical trials that have been registered with a no-cost, publicly accessible database, such as http://www.clinicaltrials.gov. The Pharmaceuticals and Research Manufacturers of America has also issued voluntary principles for its members to make results from certain clinical trials publicly available and has established a website for this purpose. Other groups have adopted or are considering similar proposals for clinical trial registration and the posting of clinical trial results. The state of Maine has enacted legislation, with penalty provisions, requiring the disclosure of results from clinical trials involving drugs marketed in the state, and similar legislation has been introduced in other states. Federal legislation was introduced in the fall of 2004 to expand http://www.clinicaltrials.gov and to require the inclusion of clinical trial results in this registry. In some states, such as New York, prosecutors have alleged that a lack of disclosure of clinical trial information constitutes fraud, and these allegations have resulted in settlements with pharmaceutical companies that include agreements to post clinical trial results. Our failure to comply with any clinical trial posting requirements could expose us to negative publicity, fines, and other penalties, all of which could materially harm our business.

Risks Related to Our Financial Performance and Operations

We have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain.

We are a development stage company with a limited operating history and no current source of revenue from the sale of our product candidates. We have incurred losses in each year since our inception in 2001, and we expect to incur losses for the foreseeable future. We have devoted, and will continue to devote for the foreseeable future, substantially all of our resources to research and development of our product candidates. For the nine months ended September 30, 2010, we had a net loss of $12.1 million and our cumulative net loss since our inception through September 30, 2010 was $219.9 million. Clinical trials are costly. We do not expect to generate any revenue from the sale of our product candidates in the near term, and we expect to continue to have significant losses for the foreseeable future.

To attain profitability, we will need to develop products successfully and market and sell them effectively. We cannot predict when we will become profitable, if at all. We have never generated revenue from the sale of our product candidates, and there is no guarantee that we will be able to do so in the future. If we fail to become profitable, or if we are unable to fund our continuing losses, we would be unable to continue our research and development programs.

We are likely to require substantial additional funding and may be unable to raise capital when needed, which could force us to delay, reduce or eliminate our drug discovery, product development and commercialization activities.

Developing drugs, conducting clinical trials, and commercializing products is expensive. Our future funding requirements will depend on many factors, including:

- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- the progress and cost of our clinical trials and other research and development activities;
- the costs and timing of obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights;

- the cost and timing of securing manufacturing capabilities for our clinical product candidates and commercial products, if any; and
- the costs of lawsuits involving us or our product candidates.

We believe that our existing cash, cash equivalents and marketable securities as of September 30, 2010 will be sufficient to fund our projected operating requirements through the second quarter of 2011, including prosecuting our current clinical trials, conducting research and discovery efforts towards additional product candidates, working capital and general corporate purposes. We expect that we will need to raise additional capital to complete clinical trials that we started in 2010 or to in-license or otherwise acquire and develop additional products or programs. We expect to seek funds through arrangements with collaborators or others that may require us to relinquish rights to certain products candidates that we might otherwise seek to develop or commercialize independently. We cannot be certain that we will be able to enter into any such arrangements on reasonable terms, if at all.

We expect to need to raise additional capital or incur indebtedness to continue to fund our future operations. We may seek to raise capital through a variety of sources, including:

- the public equity market;
- private equity financing;
- collaborative arrangements;
- licensing arrangements; and/or
- public or private debt.

Our ability to raise additional funds will depend, in part on our clinical and regulatory events, enter into collaboration or license agreement with others and factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on satisfactory terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any of which could delay or require that we curtail or eliminate some or all of our development programs or otherwise have a material adverse effect on our business, financial condition and results of operations. In addition, the Company may have to delay, reduce the scope of or eliminate some of its research and development, which could delay the time to market for any of its product candidates, if adequate funds are not available. In addition, we may have to delay, reduce the scope of or eliminate some of our research and development, which could delay the time to market for any of our product candidates, if adequate funds are not available.

If we are unable to secure additional financing on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. Insufficient funds may require us to delay, scale back, or eliminate some or all of our activities, and if we are unable to obtain additional funding, there is uncertainty regarding our continued existence.

Our success depends in part on retaining and motivating key personnel and, if we fail to do so, it may be more difficult for us to execute our business strategy. As a small organization we are dependent on key employees and may need to hire additional personnel to execute our business strategy successfully.

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly our Chief Executive Officer, Dr. Harold E. Selick, President and Chief Medical Officer, Dr. John M. Curd and Senior Vice President of Discovery Research, Dr. Mark G. Matteucci. We do not have employment agreements with Drs. Selick, Curd or Matteucci. The loss of the services of Drs. Selick, Curd or Matteucci or one or more of our other key employees could delay or have an impact on the successful completion of our clinical trials or the development of additional product candidates.

As of September 30, 2010, we had 37 employees. Our success will depend on our ability to retain and motivate remaining personnel and hire additional qualified personnel when required. Competition for qualified personnel in the biotechnology field is intense. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private research institutions and other organizations. We may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel. If we are unsuccessful in our retention, motivation and recruitment efforts, we may be unable to execute our business strategy.

Our facilities in California are located near an earthquake fault, and an earthquake or other natural disaster or resource shortage could disrupt our operations.

Important documents and records, such as hard copies of our laboratory books and records for our product candidates, are located in our corporate headquarters at a single location in Redwood City, California, near active earthquake zones. In the event of a natural disaster, such as an earthquake, drought or flood, or localized extended outages of critical utilities or transportation systems, we do not have a formal business continuity or disaster recovery plan, and could therefore experience a significant business interruption. In addition, California from time to time has experienced shortages of water, electric power and natural gas. Future shortages and conservation measures could disrupt our operations and could result in additional expense. Although we maintain business interruption insurance coverage, the policy specifically excludes coverage for earthquake and flood.

Risks Related to Our Dependence on Third Parties

We rely on third parties to manufacture TH-302. If these parties do not manufacture the active pharmaceutical ingredients or finished drug products of satisfactory quality, in a timely manner, in sufficient quantities or at an acceptable cost, clinical development and commercialization of our product candidates could be delayed.

We do not currently own or operate manufacturing facilities; consequently, we rely and expect to continue to rely on third parties for the production of clinical and commercial quantities of our product candidates. We have not yet entered into any long term manufacturing or supply agreement for any of our product candidates. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our ability to develop and commercialize any product candidates on a timely and competitive basis.

Our contract manufacturers have produced sufficient TH-302 API and drug product to meet the clinical supply demands of our ongoing clinical trials. Additional clinical trial material continues to be manufactured as required. We have ordered additional API and drug product; however, we will need to obtain additional supplies of TH-302 API and drug product to complete any other additional trials. The need for additional supplies may require manufacturing process improvements in TH-302 API and drug product. If we are not successful in procuring sufficient TH-302 clinical trial material, we may experience a significant delay in our TH-302 clinical program.

We will need to enter into additional agreements for additional supplies of each of our product candidates to complete clinical development and/or commercialize them. We cannot be certain that we can do so on favorable terms, if at all. The products will need to satisfy all cGMP manufacturing requirements, including passing specifications. Our inability to satisfy these requirements could delay our clinical programs.

If any of our product candidates is approved by the FDA or other regulatory agencies for commercial sale, we will need to have it manufactured in commercial quantities. We may not be able to increase the manufacturing capacity for any of our product candidates in a timely or economic manner successfully or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA and other regulatory agencies must review and approve. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed, or there may be a shortage of supply which could limit our sales.

In addition, if the facility or the equipment in the facility that produces our product candidates is significantly damaged or destroyed, or if the facility is located in another country and trade or commerce with such country is interrupted, we may be unable to replace the manufacturing capacity quickly or inexpensively. The inability to obtain manufacturing agreements, the damage or destruction of a facility on which we rely for manufacturing or any other delays in obtaining supply would delay or prevent us from completing our clinical trials and commercializing our current product candidates.

We have no control over our manufacturers' and suppliers' compliance with manufacturing regulations, and their failure to comply could result in an interruption in the supply of our product candidates.

The facilities used by our contract manufacturers must undergo an inspection by the FDA for compliance with current good manufacturing practice, or cGMP regulations, before the respective product candidates can be approved. In the event these facilities do not receive a satisfactory cGMP inspection for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate. In addition, our contract manufacturers, and any alternative contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA and corresponding state and foreign agencies for compliance with cGMP regulations, similar foreign regulations and other regulatory standards. We do not have control over our contract manufacturers' compliance with these regulations and standards. Any failure by our third-party manufacturers or suppliers to comply with applicable regulations could result in sanctions being imposed on them (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecution.

We rely on third parties to conduct some of our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.

We may use clinical research organizations to assist in conduct of our clinical trials. There are numerous alternative sources to provide these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. This risk is heightened for clinical trials conducted outside of the United States, where it may be more difficult to ensure that clinical trials are conducted in compliance with FDA requirements. Any third-party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials and in our plans to file NDAs, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented.

We are dependent on Eleison to develop and commercialize glufosfamide

We are dependent upon Eleison Pharmaceuticals, Inc., to whom we exclusively licensed glufosfamide in October 2009, to develop and commercialize glufosfamide. Any profit sharing or other payments to us under the Eleison license depend almost entirely upon the efforts of Eleison, which may not be able to raise sufficient funds to commence clinical development activities with glufosfamide. Even if Eleison is successful at raising initial funding, it may not be successful in developing and commercializing glufosfamide or raising sufficient funds for development and commercialization. We may also be asked to provide technical assistance related to the development of glufosfamide, which may divert our resources from other activities. If the Eleison license terminates in such a way that glufosfamide reverts to us and we seek alternative arrangements with one or more other parties to develop and commercialize glufosfamide, we may not be able to enter into such an agreement with another suitable third party or third parties on acceptable terms or at all.

Risks Related to Our Intellectual Property

Hypoxia activated prodrug technology is not a platform technology broadly protected by patents, and others may be able to develop competitive drugs using this approach.

Although we have one issued patent that covers a category of hypoxia-activated prodrugs, including TH-302, we have no issued patents or pending patent applications that would prevent others from taking advantage of hypoxia activated prodrug technology generally to discover and develop new therapies for cancer or other diseases. Consequently, our competitors may seek to discover and develop potential therapeutics that operate by mechanisms of action that are the same or similar to the mechanisms of action of our hypoxia activated prodrug product candidates.

2DG is a known compound that is not protected by patents on the composition of the molecule.

2DG is a known compound that is no longer eligible for patent protection on the composition of the molecule. A patent of this nature, known as a compound per se patent, excludes others from making, using or selling the patented compound, regardless of how or for what purpose the compound is formulated or intended to be used. Consequently, this compound and certain of its uses are in the public domain.

We have an issued U.S. patent for the use of orally administered 2DG for the treatment of cancer at certain doses and administration schedules, and we have in-licensed three issued U.S. patents that cover the treatment of certain cancers with 2DG in combination with other specific anti-cancer agents.

Others may develop and market 2DG for the treatment of cancer, however, if they develop treatments using dosing and administration schedules or combination therapies outside the scope of our patents or in contravention of our patent rights.

Targeting the increased uptake of glucose and the increased reliance on glycolysis as an energy source in cancer cells is not protected by patents, and others may be able to develop competitive drugs using this approach.

We have not issued patents or pending patent applications that would prevent others from taking advantage of targeting the increased uptake of glucose and the increased reliance of glycolysis as an energy source in solid tumors to discover and develop new therapies for cancer or other diseases. Consequently, our competitors may seek to discover and develop potential therapeutics that operate by mechanisms of action that are the same or similar to the mechanisms of action of our product candidates.

We are dependent on patents and proprietary technology, both our own and those licensed from others. If we or our licensors fail to adequately protect this intellectual property or if we otherwise do not have exclusivity for the marketing of our products, our ability to commercialize products could suffer.

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent protection sufficient to prevent others from marketing our product candidates, as well as to defend and enforce these patents against infringement and to operate without infringing the proprietary rights of others. We will only be able to protect our product candidates from unauthorized use by third parties to the extent that valid and enforceable patents cover our product candidates or their manufacture or use if they are effectively protected by trade secrets. If our patent applications do not result in issued patents, or if our patents, or those patents we have licensed, are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein. We have a limited number of patents and pending patent applications.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The laws of many countries may not protect intellectual property rights to the same extent as United States laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We do not know whether any of our patent applications will result in the issuance of any patents and we cannot predict the breadth of claims that may be allowed in our patent applications or in the patent applications we license from others.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we or our licensors might not have been the first to make the inventions covered by each of our or our licensors' pending patent applications and issued patents, and we may have to participate in expensive and protracted interference proceedings to determine priority of invention;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative product candidates or duplicate any of our or our licensors' product candidates;
- our or our licensors' pending patent applications may not result in issued patents;

- our or our licensors' issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;
- others may design around our or our licensors' patent claims to produce competitive products that fall outside the scope of our or our licensors' patents;
- we may not develop or in-license additional patentable proprietary technologies related to our product candidates; or
- the patents of others may prevent us from marketing one or more of our product candidates for one or more indications that may be valuable to our business strategy.

Moreover, an issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing the same or related product candidates or could limit the length of the term of patent protection of our product candidates. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Patent term extensions may not be available for these patents.

We rely on trade secrets and other forms of non-patent intellectual property protection. If we are unable to protect our trade secrets, other companies may be able to compete more effectively against us.

We rely on trade secrets to protect certain aspects of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secret information is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to or may not protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we are sued for infringing intellectual property rights of third parties or if we are forced to engage in an interference proceeding, it will be costly and time consuming, and an unfavorable outcome in that litigation or interference would have a material adverse effect on our business.

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general field of cancer therapies or in fields that otherwise may relate to our product candidates. We are also aware of a patent that claims certain agents, including 2DG, to inhibit the import of glucose-6-phosphate into the endoplasmic reticulum of a cell. We do not know whether administration of 2DG for our intended uses inhibits such import. If it does, we would be required to license the patent or risk that a claim of infringement could be made. If we are shown to infringe, we could be enjoined from use or sale of the claimed invention if we are unable to prove that the patent is invalid. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or any other compound that we may develop, may infringe, or which may trigger an interference proceeding regarding one of our owned or licensed patents or applications. There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe or which may become involved in an interference proceeding.

The biotechnology and biopharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. For so long as our product candidates are in clinical trials, we believe our clinical activities fall within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our clinical investigational drugs progress toward commercialization, the possibility of a patent infringement claim against us increases. While we attempt to ensure that our active clinical investigational drugs and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights, we cannot be certain they do not, and competitors or other parties may assert that we infringe their proprietary rights in any event.

We may be exposed to future litigation based on claims that our product candidates, or the methods we employ to manufacture them, or the uses for which we intend to promote them, infringe the intellectual property rights of others. Our ability to manufacture and commercialize our product candidates may depend on our ability to demonstrate that the manufacturing processes we employ and the use of our product candidates do not infringe third-party patents. If third-party patents were found to cover our product candidates or their use or manufacture, we could be required to pay damages or be enjoined and therefore unable to commercialize our product candidates, unless we obtained a license. A license may not be available to us on acceptable terms, if at all.

Risks Related To Our Industry

If our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited.

Competition in the biotechnology and pharmaceutical industries is intense and continues to increase, particularly in the area of cancer treatment. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing oncology development programs, including traditional therapies and therapies with novel mechanisms of action. Our cancer product candidates face competition from established biotechnology and pharmaceutical companies, including sanofi-aventis, AstraZeneca PLC, Genentech, Inc., Bayer Corporation, Eli Lilly and Company and Pfizer, Inc. and from generic pharmaceutical manufacturers. In particular, our drug candidates for pancreatic cancer will compete with Gemzar, marketed by Eli Lilly and Company, doxorubicin, cisplatin, paclitaxel, ifosfamide, and 5-flurouracil, or 5-FU, a generic product which is sold by many manufacturers. In addition, several drugs marketed for different indications, such as Camptosar®, marketed by Pfizer, Inc., Erbitux®, marketed by Imclone Systems Inc. and Bristol-Myers Squibb Company, Taxotere®, marketed by sanofi-aventis, DTIC-Dome®, marketed by Bayer Pharmaceuticals Corporation, Xeloda®, marketed by Hoffmann-LaRoche, Inc., Avastin®, marketed by Genentech, Inc., Nexavar®, marketed by Onyx Pharmaceuticals, Inc. and Bayer AG, and Alimta®, marketed by Eli Lilly and Company, are under investigation or have completed investigation as combination therapies or monotherapy for pancreatic, prostate, ovarian, non small cell lung and small cell lung cancers, melanoma and soft tissue sarcoma. Additionally OSI Pharmaceuticals, Inc. and Genentech, Inc. market Tarceva® as a combination therapy with gemcitabine for the first-line treatment of pancreatic cancer. In addition, Proacta Inc. has a compound under clinical investigation that targets the hypoxic zones of tumors, as our TH-302 clinical product candidate is intended to do. Novacea has conducted studies on AQ4N and sanofi-aventis recently completed a Phase 3 clinical trial on Tirapazamine, a hypoxically activated prodrug, and while Novacea has stopped current clinical development of AQ4N and sanofi-aventis has released rights to the compound to the innovator SRI, another company may pursue further clinical development of either compound. Abraxis Bioscience Inc. is conducting clinical trials of Abraxene® as a combination therapy for first-line treatment of pancreatic cancer. ZIOPHARM Oncology Inc. is conducting clinical trials of a compound as a combination therapy for first-line treatment of advanced soft tissue sarcoma.

We also face potential competition from academic institutions, government agencies and private and public research institutions engaged in the discovery and development of drugs and therapies. Many of our competitors have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing, sales and marketing than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies.

Our competitors may succeed in developing products that are more effective, have fewer side effects and are safer or more affordable than our product candidates, which would render our product candidates less competitive or noncompetitive. These competitors also compete with us to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registration for clinical trials, as well as to acquire technologies and technology licenses complementary to our programs or advantageous to our business. Moreover, competitors that are able to achieve patent protection obtain regulatory approvals and commence commercial sales of their products before we do, and competitors that have already done so, may enjoy a significant competitive advantage.

There is a substantial risk of product liability claims in our business. If we do not obtain sufficient liability insurance, a product liability claim could result in substantial liabilities.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or failure to complete our clinical trials;
- withdrawal of clinical trial participants;
- decreased demand for our product candidates;
- injury to our reputation;
- litigation costs;
- substantial monetary awards against us; and
- diversion of management or other resources from key aspects of our operations.

If we succeed in marketing products, product liability claims could result in an FDA investigation of the safety or efficacy of our products, our manufacturing processes and facilities or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, or limitations on the indications, for which they may be used, or suspension or withdrawal of approval.

We have product liability insurance that covers our clinical trials up to a $5 million annual aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates or any other compound that we may develop. However, insurance coverage is expensive and we may not be able to maintain insurance coverage at a reasonable cost or at all, and the insurance coverage that we obtain may not be adequate to cover potential claims or losses.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which would negatively affect our ability to achieve profitability.

Our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the effectiveness of the product;
- the prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the price of the product, both in absolute terms and relative to alternative treatments; and
- sufficient third-party coverage or reimbursement.

If our product candidates receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate product revenues sufficient to attain profitability.

If third-party payors do not adequately reimburse patients for any of our product candidates, if approved for marketing, we may not be successful in selling them.

Our ability to commercialize any products successfully will depend in part on the extent to which reimbursement will be available from governmental and other third-party payors, both in the United States and in foreign markets. Even if we succeed in bringing one or more products to the market, the amount reimbursed for our products may be insufficient to allow us to compete effectively and could adversely affect our profitability.

Reimbursement by a governmental and other third-party payor may depend upon a number of factors, including a governmental or other third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each third-party and governmental payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to obtain reimbursement.

Eligibility for coverage does not imply that any drug product will be reimbursed in all cases or at a rate that allows us to make a profit. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not become permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost drugs that are already reimbursed, may be incorporated into existing payments for other products or services and may reflect budgetary constraints and/or Medicare or Medicaid data used to calculate these rates. Net prices for products also may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

The health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, or MMA, became law in November 2003 and created a broader prescription drug benefit for Medicare beneficiaries. The MMA also contains provisions intended to reduce or eliminate delays in the introduction of generic drug competition at the end of patent or nonpatent market exclusivity. The impact of the MMA on drug prices and new drug utilization over the next several years is unknown. The MMA also made adjustments to the physician fee schedule and the measure by which prescription drugs are presently paid, changing from Average Wholesale Price to Average Sales Price. The effects of these changes are unknown but may include decreased utilization of new medicines in physician prescribing patterns, and further pressure on drug company sponsors to provide discount programs and reimbursement support programs. There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect reimbursement levels for our future products. In addition, the Centers for Medicare & Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our profitability will be negatively affected.

We may incur significant costs complying with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

Our research and development activities use biological and hazardous materials that are dangerous to human health and safety or the environment. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes resulting from these materials. We are also subject to regulation by the Occupational Safety and Health Administration, or OSHA, the California and federal environmental protection agencies and to regulation under the Toxic Substances Control Act. OSHA or the California or federal Environmental Protection Agency, or EPA, may adopt regulations that may affect our research and development programs. We are unable to predict whether any agency will adopt any regulations that could have a material adverse effect on our operations. We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with these laws and regulations.

Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could significantly exceed our insurance coverage.

We may not be able to conduct, or contract with others to conduct, animal testing in the future, which could harm our research and development activities.

Certain laws and regulations relating to drug development require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

Risks Related To Our Common Stock

We may not maintain the listing of our common stock on the NASDAQ Capital Market.

Our ability to raise additional capital may be dependent upon our stock being quoted on the NASDAQ Capital Market. Previously, we had fallen out of compliance with continued listing requirements because our common stock did not comply with the $1.00 minimum bid price requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(a)(1) (formerly Rule 4450(a)(5)). To regain compliance, effective August 20, 2008, we implemented a 1-for-6 reverse stock split of our common stock. After that date, our common stock traded above the minimum $1.00 bid price for at least ten consecutive business days and on September 5, 2008, the NASDAQ Stock Market notified us that we had regained compliance with the minimum bid price requirements. Even though we regained compliance with the minimum bid price, we cannot assure you that we will be able to maintain compliance with the minimum bid price requirement or other listing requirements in the future, and our failure to do so could result in the delisting of our shares from the NASDAQ Capital Market.

A significant number of shares of our common stock are subject to issuance upon exercise of outstanding warrants, which upon such exercise would result in dilution to our security holders.

On October 5, 2009, we issued outstanding warrants to purchase an aggregate of 7,329,819 shares of our common stock, at an exercise price of $2.23 per share. In addition, on August 29, 2008, we issued outstanding warrants to purchase an aggregate of 3,588,221 shares of our common stock, at an exercise price of $2.34 per share, which exercise price was subsequently reduced to $1.86 per share on October 5, 2009 under the anti-dilution provisions of the warrants as a result of our October 2009 private placement. The exercise price and/or the number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances, including certain issuances of securities at a price equal to less than the then current exercise price (which could happen, for example, in connection with sales of stock under our at market issuance sales agreement dated October 29, 2010), subdivisions and stock splits, stock dividends, combinations, reorganizations, reclassifications, consolidations, mergers or sales of properties and assets and upon the issuance of certain assets or securities to holders of our common stock, as applicable. Although we cannot determine at this time which of these warrants will ultimately be exercised, it is reasonable to assume that such warrants will be exercised only if the exercise price is below the market price of our common stock. To the extent the warrants are exercised, additional shares of our common stock will be issued that will be eligible for resale in the public market, which will result in dilution to our security holders. The issuance of additional securities could also have an adverse effect on the market price of our common stock.

The price of our common stock has been and may continue to be volatile.

The stock markets in general, the markets for biotechnology stocks and, in particular, the stock price of our common stock, have experienced extreme volatility.

Price declines in our common stock could result from general market and economic conditions and a variety of other factors, including:

- adverse results or delays in our clinical trials;
- announcements of FDA non-approval of our product candidates, or delays in the FDA or other foreign regulatory agency review process;
- adverse actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing processes or sales and marketing activities;
- announcements of technological innovations, patents or new products by our competitors;
- regulatory developments in the United States and foreign countries;
- any lawsuit involving us or our product candidates;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;
- developments concerning any strategic alliances or acquisitions we may enter into;
- actual or anticipated variations in our operating results;
- changes in recommendations by securities analysts or lack of analyst coverage;
- deviations in our operating results from the estimates of analysts;
- sales of our common stock by our executive officers, directors and five percent stockholders or sales of substantial amounts of common stock; and
- loss of any of our key scientific or management personnel.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. Any such lawsuit could consume resources and management time and attention, which could adversely affect our business.

If our officers, directors and largest stockholders choose to act together, they may be able to control our management and operations, acting in their best interests and not necessarily those of other stockholders.

As of September 30, 2010, our officers, directors and other affiliates beneficially owned in excess of 25.0% of our common stock, assuming the full exercise of all outstanding warrants. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of Delaware law, where we are incorporated, our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;
- providing for a classified board of directors with staggered terms;
- requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;
- eliminating the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, in August 2006, our board of directors adopted a preferred shares rights agreement, the provisions of which could make it more difficult for a potential acquirer to consummate a transaction without the approval of our board of directors.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

(c) Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. RESERVED

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibits

The exhibits listed on the accompanying index to exhibits are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 to our Registration Statement on Form S-1, as amended (File No. 333-114376), filed on April 9, 2004)
3.2	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.4 to our Annual Report on Form 10-K filed on March 13, 2009)
3.3	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a) of Harold E. Selick.
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a) of Joel A. Fernandes.
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Harold E. Selick.
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Joel A. Fernandes.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Threshold Pharmaceuticals, Inc.

Date: November 4, 2010

/S/ HAROLD E. SELICK

Harold E. Selick., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 4, 2010

/S/ JOEL A. FERNANDES

Joel A. Fernandes
Senior Director, Finance and Controller
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

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32.2	Certification pursuant to 18 U.S.C. Section 1350 of Joel A. Fernandes.

Exhibit 3.3

CERTIFICATE OF AMENDMENT

OF THE

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

THRESHOLD PHARMACEUTICALS, INC.

The undersigned, Dr. Harold E. Selick, hereby certifies that:

1. He is the Chief Executive Officer of Threshold Pharmaceuticals, Inc., a Delaware corporation (the "Corporation").

2. The original Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on October 17, 2001.

3. Article Fourth, Paragraph A of the Corporation's Amended and Restated Certificate of Incorporation is amended and restated in its entirety to read as follows:

"A. The total number of shares of all classes of stock which the Corporation shall have authority to issue is 152,000,000, consisting of 150,000,000 shares of Common Stock, par value $0.001 per share (the "Common Stock") and 2,000,000 shares of Preferred Stock, par value $0.001 per share (the "Preferred Stock")."

4. This Certificate of Amendment of the Corporation's Amended and Restated Certificate of Incorporation has been duly adopted by this Corporation's Board of Directors and stockholders in accordance with the provisions of the Corporation's Amended and Restated Certificate of Incorporation and with Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Amendment of Amended and Restated Certificate of Incorporation at Redwood City, California on May 25, 2010.

/s/ Harold E. Selick
Harold E. Selick, Ph.D.
Chief Executive Officer

Exhibit 31.1

CERTIFICATION

I, Harold E. Selick, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Threshold Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2010

/s/ Harold E. Selick
Harold E. Selick, Ph.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Joel A. Fernandes, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Threshold Pharmaceuticals, Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2010

/s/ Joel A. Fernandes
Joel A. Fernandes
Senior Director, Finance and Controller
(Principal Financial and Accounting Officer)

Exhibit 32.1

THRESHOLD PHARMACEUTICALS, INC.

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Threshold Pharmaceuticals, Inc (the "Company") on Form 10-Q for the quarter ended September 30, 2010, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Harold E. Selick, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This Certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission.

Date: November 4, 2010

/s/ Harold E. Selick
Harold E. Selick, Ph.D.
Chief Executive Officer

Exhibit 32.2

THRESHOLD PHARMACEUTICALS, INC.

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Threshold Pharmaceuticals, Inc (the "Company") on Form 10-Q for the quarter ended September 30, 2010, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joel A. Fernandes, Senior Director, Finance and Controller of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This Certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission.

Date: November 4, 2010

/s/ Joel A. Fernandes
Joel A. Fernandes
Senior Director, Finance and Controller
(Principal Financial and Accounting Officer)